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Case Docket No. PFE-004

06-09-00
Transmitted herewith for filing is the patent application of

Inventor(s): John Edward Pfeifer and Peter Rising

For: AMPOULE ANALYZER APPARATUS

Enclosed are:

- | | |
|---------------------------------------|---|
| <input type="checkbox"/> 3 | Sheets of drawings |
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| <input type="checkbox"/> | Assignment of Invention to: |
| <input checked="" type="checkbox"/> X | Statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 |
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INDEP CLAIMS	2 - 3	0	X 39			X 78
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JC530 U.S. PTO
09/09/00
06/08/00

Docket No. PFE-004

STATEMENT CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9(f) and 1.27(b)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby state that I am an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41 (a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled:

AMPOULE ANALYZER APPARATUS

described in the specification filed herewith
 application serial No. , filed
 patent No. , issued

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey or license any rights in the invention is listed below:

no such person, concern, or organization
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*Note: Separate statements are required from each named person, concern or organization having rights to the invention according to their status as small entities. (37 CFR 1.27)

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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby state that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this statement is directed.

NAME OF INVENTOR: John Edward Pfeifer

SIGNATURE

DATE

6/5/00

NAME OF INVENTOR: Peter E. Rising

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DATE

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PAGE 04

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NAME OF INVENTOR: John Edward Pfeifer

SIGNATURE

DATE

NAME OF INVENTOR: Peter E. Rising

SIGNATURE

DATE

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: John Edward Pfeifer et al.

SERIAL NO.:

GROUP ART UNIT:

FILED: June 8, 2000

EXAMINER:

FOR: Ampoule Analyzer Apparatus

ATT'Y DOCKET NO.: PFE-004

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

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1 AMPOULE ANALYZER APPARATUS
2

3 This application is a continuation-in-part of both U.S.
4 Serial No. 09/557,653, filed April 25, 2000, and U.S. Serial No.
5 09/578,323, entitled "Light Analyzer Apparatus" and filed May 24,
6 2000, which are both hereby incorporated by reference herein in
7 their entireties.

8

9 BACKGROUND OF THE INVENTION
10

11 1. Field of the Invention

12 This invention relates broadly to analytical instruments.
13 More particularly, this invention relates to an analyzer apparatus
14 for determining when a photometric change occurs in a sample, and
15 relating the change to a condition of the sample at a previous
16 time.

17

18 2. State of the Art

19 Water quality, and particularly bacterial content in water is
20 of great concern. Municipalities perform periodic checks of water
21 quality to ensure that water reserves are safe. Recently, home
22 monitoring of water quality has become popular.

23

24 A number of products are available for testing water quality.
25 One variety of product is an ampoule which is a sealed evacuated

1 vial containing a powdered nutrient for microbes and an indicator
2 which changes color when the concentration of microbes reaches a
3 specific high level. One such ampoule is shown in U.S. Patent No.
4 5,935,799 to Isbister. In use, a user inverts the ampoule in a
5 cup of sample water and breaks off a scored tip of the ampoule.
6 The vacuum in the ampoule causes the ampoule to fill with sample
7 water. The ampoule is then shaken to mix the powdered nutrient
8 and indicator with the water. Finally, the ampoule must be
9 maintained at a constant temperature, e.g., 34°C, for a relatively
10 long period of time, e.g., up to 12 hours. One manner often
11 suggested by manufacturers of the ampoules for maintaining proper
12 temperature is for the user to place the ampoule in a shirt pocket
13 of the user, since the shirt pocket is approximately at the
14 desired temperature. Periodically, e.g., every thirty minutes,
15 the user must look for the indicator to change color by holding
16 the ampoule up the light and comparing the observed color against
17 a printed chart. When the color change is observed, the elapsed
18 time is recorded and a second chart is used to look up the number
19 of microbes that were in the original sample water based upon the
20 recorded time.

21

22 The determination of the number of microbes is based on the
23 fact that microbes multiply by binary fission. The number of
24 microbes in the original sample may therefore be determined by
25 reference to an exponential chart and the recorded time.

1 While this type of analytical product is useful, it has
2 several drawbacks. One problem is the requirement to hold the
3 ampoule in a shirt pocket for incubation. Another problem is that
4 the accuracy is questionable, as human judgment is required to
5 read the color at the end point.

6

7 Several apparatus have been disclosed to test samples, but
8 they do not address the testing requirements for the above
9 described ampoules. For example, U.S. Patent No. 5,013,155 to
10 Rybak discloses an apparatus which determines a specific color of
11 a sample in a vial received in a receptacle in the apparatus. The
12 device uses two light sources, each of a different color, which
13 are alternately pulsed, and respective photodetectors. The
14 results are interpolated along with signals present when no light
15 is emitted, to identify the specific color of the test sample.
16 The Rybak apparatus requires a vial of clear distilled water to
17 calibrate the instrument. In addition, the device is not adapted
18 for heating test vials at a constant temperature.

19

20 U.S. Patent No. 5,959,738 to Hafeman et al. uses either a
21 single light source capable of operating at multiple wavelengths,
22 or multiple and different wavelength light sources. A
23 relationship is determined between the light absorption properties
24 of a liquid sample (solvent and analyte) and the optical
25 pathlength of the liquid sample to calculate a concentration of an

1 analyte in a solvent of the sample. The device is not capable of
2 determining when a change occurs in the contents of an ampoule
3 when the contents of an ampoule are already known.

4

Therefore, what is required is a device adapted to determine biological activity as a result of a decrease in light passage through a sample over time.

8

SUMMARY OF THE INVENTION

10

11 It is therefore an object of the invention to provide a
12 apparatus for determining when a particular change in the contents
13 of an ampoule occurs via photometric measurements.

14

15 It is another object of the invention to use a single
16 wavelength light source which functions as both a reference beam
17 and a measuring beam.

18

19 It is a further object of the invention to provide an
20 apparatus which centralizes all componentry of the light emission
21 and detection system.

22

23 It is an additional object of the invention to provide an
24 apparatus which is substantially free from error due to ambient
25 light.

1 It is also an object of the invention to provide an
2 apparatus which determines at time at which a targeted photometric
3 change occurs in a sample, and relating the targeted change to a
4 condition of the sample at a previous time.

5

6 It is yet another object of the invention to provide an
7 apparatus which maintains ampoules at a desired temperature.

8

9 It is yet a further object of the invention to provide a
10 portable and relatively low cost apparatus for heating and
11 analyzing changes in the contents of an ampoule.

12

13 In accord with these objects, which will be discussed in
14 detail below, an ampoule analyzer apparatus is provided which
15 includes a housing having at least one receptacle (or nest) for an
16 ampoule, a cover for substantially preventing ambient temperature
17 and light from affecting each receptacle, a light analysis system,
18 an incubation system, and a master control system.

19

20 The light analysis system includes, for each receptacle, at
21 least one light source and a photodetector positioned such that
22 the light from the light source passes through the receptacle (and
23 thereby the ampoule and its contents) prior to entering the
24 photodetector. The light source is chosen to deliver a
25 predetermined wavelength of light such that the color change of

1 the contents of the ampoule causes reduction in the intensity of
2 the light transmitted through the contents of the ampoule.

3

4 The incubation system includes, for each receptacle, a
5 heating element which rapidly heats the receptacle to a desired
6 temperature and a temperature sensor which senses the temperature
7 of the receptacle. Each receptacle is preferably insulated to
8 prevent unintended heating of neighboring receptacles of the
9 apparatus.

10

11 The master control system permits user input, operates the
12 light analysis system and the incubation system. In addition, the
13 master control system includes a timer, and a memory provided with
14 a look-up table relating the type of test, the time to test
15 completion, and the associated bacterial count at the start of the
16 test. A user-readable display for the output of the results,
17 e.g., the bacterial count at time zero, is also provided.

18

19 During operation, an ampoule containing a water sample and a
20 reagent which causes the sample to change color when a certain
21 level of biological activity is present in the sample is placed
22 within one of the receptacles. The light analysis system is
23 operated to transmit light at the predetermined wavelength through
24 the ampoule (either axially or transversely) to the detector, and
25 a maximum amount (intensity) of light passing through the ampoule

1 is determined. The incubation system is also operated to heat the
2 receptacle and the ampoule therein to a desired test temperature
3 and the timer is started. The light analysis system periodically
4 transmits light through the ampoule. Increased biological
5 activity in the sample causes a color change to the indicator
6 which reduces light transmission through the ampoule. When the
7 light detected at the detector is reduced relative to the light
8 transmitted by a predetermined percentage of the maximum amount of
9 light, the master control system signals that the test is
10 complete. Based on the amount of time required for this to occur,
11 the master control system determines from the look-up table the
12 bacterial content in the sample at the beginning of the test and
13 displays the results on the display.

14

15 The apparatus may include a large number of receptacles
16 suitable for laboratory use or may include fewer or one receptacle
17 suitable for home or portable use.

18

19 Additional objects and advantages of the invention will
20 become apparent to those skilled in the art upon reference to the
21 detailed description taken in conjunction with the provided
22 figures.

23

1 BRIEF DESCRIPTION OF THE DRAWINGS
23 Fig. 1 is a schematic circuit diagram of the apparatus of the
4 invention;

5

6 Fig. 2 is a partial side view of the apparatus of the
7 invention showing the case lid in open and closed positions;

8

9 Fig. 3 is a partial front view of the analyzer apparatus of
10 the invention;

11

12 Fig. 4 is a top view of the apparatus of the invention
13 without the case lid;

14

15 Fig. 5 is a side view of an ampoule receptacle according to
16 the invention;

17

18 Fig. 6 is a front view of an ampoule receptacle according to
19 the invention; and

20

21 Fig. 7 is a flow chart illustrating the operation of the
22 apparatus of the invention.

23

1 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS
2

3 Turning now to Figs. 1 through 4, an ampoule analyzer
4 apparatus 10 according to the invention includes a housing 12
5 having a light analysis system (a light source 14 and an optical
6 detector 16, collectively), an incubation system (a heating
7 element 18 and a sensor chip 19, collectively), and a master
8 control system 20, each of which is discussed in detail below.

9 The housing 12 also includes a battery 24 and associated circuitry
10 26 to power the various systems. A preferred battery 24 and
11 circuitry 26 are disclosed in previously incorporated U.S. Serial
12 No. 09/578,323.

13

14 Six receptacles (nests) 30, each for receiving an ampoule 32,
15 are provided in the housing. The housing 12 is also preferably
16 provided with a planar lower surface 34 which is adapted to seat
17 the housing on a planar surface, and a storage area 36 for storing
18 ampoules or other items. A lid 38 movable between closed and open
19 (broken lines) positions covers and uncovers the receptacles 30,
20 the storage area 36, and other exposed components to protect them
21 from the elements, and to facilitate transportation of the
22 apparatus.

23

24

25

1 A receptacle cover 40 in an open position provides access to
2 the receptacles 30 and in a closed position 40a substantially
3 individually seals each receptacle to prevent ambient light from
4 affecting the receptacle. The receptacle cover 40 preferably
5 includes a plurality of concave portions 42 each having a diffuse
6 reflective interior surface 44 which reflects and distributes
7 light from a light source, discussed below, through the
8 receptacles.

9

10 Each receptacle 30 is an opaque tube; e.g., metal or plastic,
11 approximately 0.5 - 0.625 inch in diameter, and preferably
12 approximately four inches in length. The receptacles 30 are
13 individually surrounded by a thermally insulative foam 46 to
14 maintain the temperature of the receptacle during heating by the
15 incubation system, as described below. Turning to Figs. 5 and 6,
16 a transparent preferably cleanable disk 48, preferably glass or
17 polycarbonate, is provided near a lower end 30a of the receptacle.
18 The closed end 32a of the ampoule 32 is provided near the disk 48,
19 with the open end 32b of the ampoule at the upper end 30b of the
20 receptacle (Fig. 2). An O-ring 50 provides a watertight seal
21 between the disk 48 and the interior surface of the receptacle 30.
22 A weep hole 51 is provided in the receptacle adjacent but above
23 the location of the disk 48 to permit any water, test solution, or
24 cleaning/sterilization solution which may drip into the receptacle
25 30 to drain therefrom.

Referring to Figs. 1, 2 and 5, the receptacles 30 are attached to a printed circuit board (PCB) 52, e.g., by screws 54, preferably such that a longitudinal axis of each receptacle runs parallel to the plane of the PCB. Each receptacle 30 is provided with the light source 14 and the optical detector 16 which are each electrically coupled to a microcontroller 60 of the master controller 20. Both the light source 14 and optical detector 16 are also preferably physically coupled to the PCB 52. The light source 14 includes one or more LEDs adapted to emit light at a predetermined wavelength into the receptacle 30 when receiving a signal 54 from the microcontroller 60. According to a preferred embodiment of the invention, the light source 14 is a plurality of LEDs coupled to the PCB 52 in an orientation such that they preferably direct light into the reflective interior surface 44 of the associated portion 42 of the cover 40 of housing 12. The reflective surface 44 scatters the light of the LEDs 14 substantially axially through the ampoule 32 in the receptacle 30 and toward the detector 16 located at the lower end 30a of the receptacle (Figs. 1 and 2). A preferably hemispherical lens 56 is preferably provided to gather the scattered light and channel the light transmitted through the ampoule 32 toward the detector 16 (Figs. 5 and 6). The optical detector 16 provides a return signal 58 to the microcontroller 60. The return signal 58 is amplified and filtered with a time constant to null out any short term changes which may be caused by bubbles breaking at the top

1 surface. The analog return signal is provided to an analog to
2 digital converter associated with the microcontroller 60.

3

4 The receptacles 30 are preferably provided at an oblique,
5 non-perpendicular angle relative to both the vertical and the
6 horizontal, e.g., 30° to 45° off vertical, by angling the
7 receptacles relative to the lower surface 34 of the housing 12.

8 The angle of the receptacles 30 facilitates axial light
9 transmission through the ampoules by preventing sediment from
10 accumulating on the entire bottom of the ampoule and thereby
11 blocking all light paths between the reflective surface 44 and the
12 optical detector 16. Moreover, the ampoules are preferably
13 provided with a stirring rod which will settle outside a direct
14 axial light path when the receptacles are angled. As the
15 receptacles 30 are preferably coupled to the PCB 52, one preferred
16 manner of providing the angle is to orient the entire PCB at the
17 desired angle relative to vertical within the housing 12. The
18 above described configuration of the light source 14, optical
19 detector 16, and orientation of the receptacles 30 provides a
20 system in which all componentry is preferably provided at or below
21 the level of the top 32b of the ampoule 32. This configuration
22 facilitates sealing the receptacles 30 from ambient light, with
23 the reflective surface 44 of the cover 40 providing the
24 redirection of the light into the required path through the
25 receptacle and ampoule. In addition, as the cover 40 is capable

1 of reflecting the light, the need for separate reflectors is
2 obviated and a system with fewer components, and therefore lower
3 cost, is provided.

4

5 As briefly discussed above, the light source 14, preferably a
6 plurality of LEDs, is adapted to emit light at a predetermined
7 wavelength. Optionally, the LEDs may emit light at different
8 wavelengths, and then, depending upon which wavelength is desired,
9 the LED which produces light at that wavelength is selected. In
10 addition, the master control system 20 may be operated to cause
11 the microcontroller 60 to signal all the LEDs of the light source
12 14 to emit light constantly, alternately, or to be pulsed.

13

14 Still referring to Figs. 1, 2 and 5, the incubation system
15 includes the heating element 18 adapted to heat the receptacle 30
16 and a temperature sensor chip 19 in contact with the receptacle 30
17 for determining the temperature thereof. The heating element 18
18 includes a pack of heating resistors 66 and a driver FET (field
19 effect transistor) 68 which is also coupled to the microcontroller
20 60 of the master control system 20. The temperature sensor chip
21 19 is preferably a silicon device which produces a voltage related
22 to a sensed temperature. The sensor chip 19 is preferably held
23 tightly against the receptacle 30 to accurately sense the
24 temperature of the receptacle. Preferably, one of the screws 54
25 provides a heat conductive path from the receptacle 30 to the

1 temperature sensor 19, and a tie wrap 70 preferably sandwiches the
2 heating resistors 66 between the PCB 42 and the receptacle 14
3 (Fig. 5). The incubation system is preferably calibrated to
4 quickly and accurately heat the receptacle (and consequently the
5 ampoule provided therein) to a desired temperature. Calibration
6 of the incubation system, as well as software control and
7 associated control signals 72, 74 to and from the heating element
8 18 and sensor chip 19 to bring and maintain the receptacle 30 to a
9 desired temperature, are discussed in detail in co-pending and
10 previously incorporated U.S. Serial No. 09/557,653.

11

12 Referring back to Fig. 1, the master control system 20 of the
13 analyzer apparatus 10 includes the microcontroller 60, a timer,
14 and a control button 76 permitting user input and operation. In
15 addition, the master controller 20, through the microcontroller 60
16 operates the light analysis system 14, 16 and the incubation
17 system 18, 19, and provides information to a user-readable display
18 80 and a signal 82 to an audio output 84 (comprised of a driver
19 chip 86 and a sound transducer 88) for the output of the results
20 of testing with the analyzer.

21

22 The ampoules 32 used in the apparatus, the operation of which
23 is discussed below, contain a water sample and a reagent which
24 changes color (a color indicator) when a certain level of
25 biological activity (total microbial count, E. Coli, Coliform,

1 etc.) is present. Numerous such reagents are disclosed in detail
2 in U.S. Patent Nos. 4,204,037 to Frosch et al., 4,332,769 to Rampy
3 et al., 5,212,876 to Turner et al., and 5,935,799 to Isbister,
4 each of which is hereby incorporated by reference herein in its
5 entirety. For each type of ampoule, an ampoule calibration is
6 performed to determine the percentage of light reduction which
7 occurs at a particular light wavelength when the indicator turns
8 sufficient color to indicate an end of test. For example, an
9 ampoule containing a reagent used to indicate the total microbial
10 count in a sample has been shown to reduce light transmission to
11 seventy-five percent of the maximum light transmission through a
12 sample by its color change at test end. The types of ampoules,
13 and the predetermined amount of light transmission reduction at
14 particular light wavelengths required to indicate test completion
15 is stored in a memory of the master control system 20.

16

17 Turning now to Fig. 1, 2 and 7, in operation, an ampoule 32
18 is placed at 100 in a receptacle 30 of the apparatus 10. The
19 master controller is operated at 102 to indicate a type of
20 ampoule; i.e., reagent and test being performed. The incubation
21 system is then activated at 104 to begin bringing the ampoule to
22 the desired test temperature, e.g., 34 °C, which increases the
23 biological activity in the sample. In addition, the light
24 analysis system is operated at 106 to transmit light at a
25 predetermined wavelength, selected for the ampoule under test,

1 through the ampoule to the detector. The light level (intensity)
2 measured by the photodetector and logged at 108 at regular
3 intervals, e.g., every minute. The light transmission through the
4 ampoule may initially increase, as small bubbles rise out and
5 larger bubbles break at the surface. Once the light level stops
6 rising at 110, the light level is logged and indicated at 112 as
7 the maximum amount of light transmission that can be expected
8 through the ampoule. This self-calibration test is carried out
9 for each ampoule in each receptacle.

10

11 Meanwhile, the temperature sensor chip 19 reads at 114 the
12 temperature of the receptacle. When the chip 19 senses at 116
13 that the temperature of the ampoule is close to the target
14 temperature, e.g., within one to five degrees Celsius of the
15 target temperature, the timer is activated at 118 to begin
16 counting time until the indicator changes color sufficient to
17 reduce the light transmission to a predetermined percentage of the
18 maximum.

19

20 The detection of the indicator color changes is enhanced by
21 the choice of the light source wavelength. For example, an
22 ampoule for testing the total microbial count turns red as the
23 microbial count rises. As such, 565 nm green LEDs are preferred
24 for light transmission through the ampoule in such a test, as the
25 red reagent indicator effectively limits transmission of 565 nm

1 light therethrough. The LED color (i.e., light wavelength) is
2 selected by the master control system 20 based upon the type of
3 ampoule selected. In addition, as the sample may contain some
4 degree of turbidity; i.e., debris or small air bubbles that will
5 scatter light, it has been found that the preferred green
6 wavelength is relatively insensitive to the light scattering
7 effects of turbidity. Furthermore, as stated above, the effect of
8 turbidity is also limited by the initial self-calibration.

9

10 Periodically, e.g., every minute to every hour, light is
11 transmitted at 120 by the light source through the ampoule. This
12 continues at 122 until the color change in the reagent is
13 sufficient to reduce at 124 light transmission of the selected
14 wavelength by a predetermined amount and indicates the test is
15 complete at 126. The timer is then stopped at 128. It is noted
16 that at no time during the test is a human visual comparison
17 between the color of the contents of the ampoule and a reference
18 required. Based on the amount of time required for test
19 completion, the master control system 20 determines at 130 from a
20 look-up table stored in memory the bacterial content in the sample
21 at the beginning of the test and displays at 132 the results on
22 the display 80. The result is preferably displayed until a new
23 test is started or the power switch is turned off.

24

1 According to a second embodiment of the apparatus,
2 substantially similar to the first, the light source and light
3 detector are located on opposite sides of the receptacle rather
4 than at the ends thereof. As such, light is transmitted
5 transaxially across the receptacle and through the ampoule. The
6 apparatus of the second embodiment is used in substantially the
7 same manner as the first embodiment. However, it is noted that
8 the samples in some ampoules under test may contain microbes that
9 form various films at different levels within the ampoule; i.e., a
10 stratification of the sample. As such, the axial embodiment is
11 preferred as it eliminates any artifacts caused by stratified
12 layers. In addition, the axial measurement embodiment permits the
13 light to be transmitted through about four inches of the sample
14 water, as opposed to about 0.5 inch of water with the transaxial
15 mode. The larger amount of sample water provides a proportionally
16 denser color change when the indicator changes color.

17

18 There have been described and illustrated herein embodiments
19 of an analyzer apparatus. While particular embodiments of the
20 invention have been described, it is not intended that the
21 invention be limited thereto, as it is intended that the invention
22 be as broad in scope as the art will allow and that the
23 specification be read likewise. Thus, while a battery and
24 associated circuitry have been disclosed, it will be appreciated
25 that other power systems may be used as well. In addition, while

1 a particular calibration system has been disclosed for the
2 incubation system, other incubator calibration systems may be used
3 as well. In addition, while the temperature sensor is described
4 as producing a voltage proportional to a sensed temperature, it
5 may alternatively produce a voltage inversely proportional to a
6 sensed voltage, each of which is considered 'proportional' in the
7 claims. Also, while a field effect transistor is preferred as
8 part of the heating element, other transistors, such as a
9 switching transistor, may also be used. In addition, while the
10 receptacles are preferably made entirely from a heat conductive
11 material, it will be appreciated that only elements of the
12 receptacle need be made from a heat conductive material. For
13 example, the receptacle may alternatively include a coiled heating
14 element which resides in the interior of the receptacle and which
15 is in contact with the heating element. Furthermore, while the
16 apparatus has been described using ampoules and reagents and light
17 wavelengths suitable for testing for total microbial count in a
18 sample, it will be appreciated that other ampoules testing for
19 E. coli, Coliforms, and other biological and chemical presences
20 can also be used. Furthermore, while a preferred incubation
21 temperature of 34 °C is disclosed, it will be appreciated that
22 other temperature about 34 °C are suitable, e.g., 32 °C - 37 °C,
23 for a total microbial test, and that other temperatures may be
24 preferred for other tests. In addition, while the apparatus has
25 been described with six independently operable receptacles, the

1 apparatus may include a larger number (e.g., 24 to 36) of
2 receptacles such that it is suitable for laboratory use or may
3 include fewer or one receptacle suitable for home or portable use.
4 It will therefore be appreciated by those skilled in the art that
5 yet other modifications could be made to the provided invention
6 without deviating from its spirit and scope as claimed.

Claims:

1. A light analyzer apparatus for use with an ampoule, comprising:
 - a) a housing having a receptacle which receives the ampoule;
 - b) a light source which transmits light at a first intensity level into said receptacle;
 - c) a detector which detects at least some of said light transmitted into said receptacle; and
 - d) a control means for automatically determining when said light detected is at a predetermined percentage of said first intensity level of said light.
2. A light analyzer apparatus according to claim 1, wherein:
said housing includes a plurality of receptacles, each having a light source and a detector.
3. A light analyzer apparatus according to claim 1, further comprising:
 - e) means for heating said receptacle to a predetermined temperature.
4. A light analyzer apparatus according to claim 1, wherein:
said control means also includes a timer.

5. A light analyzer apparatus according to claim 1, wherein:
said control means also includes a memory provided with a
look-up table relating a time required for performing a test on
the ampoule in said apparatus and a biological activity in the
ampoule at a start of the test.

6. A light analyzer apparatus according to claim 5, further
comprising:

e) a display for indicating the biological activity in the
ampoule at the start of the test.

7. A light analyzer apparatus according to claim 1, further
comprising:

e) the ampoule, said ampoule containing a sample and a reagent
which changes color when a predetermined level of biological
activity is present in said sample.

8. A light analyzer apparatus according to claim 7, wherein:

said light source is selected to deliver a predetermined
wavelength of light such that the color change of the reagent
causes a reduction in the intensity level of the light transmitted
through said sample.

9. A light analyzer apparatus according to claim 1, wherein:
said light source and said detector are located on opposite
sides of said receptacle.
10. A light analyzer apparatus according to claim 9, wherein:
said light source and said detector are located on axially
opposite sides of said receptacle.
11. A light analyzer apparatus according to claim 1, wherein:
said housing includes a cover movable between open and closed
positions, and in said closed position said cover substantially
completely shields said receptacle from ambient light.
12. A light analyzer apparatus according to claim 1, wherein:
said light source is at least one LED.
13. A light analyzer apparatus according to claim 12, wherein:
said light source is at least one green LED.
14. A light analyzer apparatus according to claim 1, wherein:
said green LED is adapted to emit light at approximately
565 nm.

15. A method of analyzing contents of an ampoule, the ampoule containing a sample and a reagent which changes color when a predetermined level of biological activity is present in the sample, said method comprising:

- a) recording a maximum intensity of light transmitted through said ampoule;
- b) identifying a first time;
- c) transmitting light at a predetermined wavelength through said ampoule;
- d) identifying an end time relative to said first time at which an intensity of said light transmitted at said predetermined wavelength through the ampoule is at a predetermined percentage of said maximum intensity of light; and
- e) automatically determining from said end time a level of biological activity present in the sample at said first time.

16. A method according to claim 15, wherein:

said recording includes transmitting light at said predetermined wavelength at regular intervals and identifying when said intensity of light transmitted through said ampoule stops increasing.

17. A method according to claim 15, wherein:

said predetermined wavelength is 565 nm.

18. A method according to claim 15, wherein:

said transmitting light transmits light axially through said ampoule.

19. A method according to claim 15, wherein:

said automatically determining includes referencing a look-up table in a memory.

20. A method according to claim 15, further comprising:

g) heating the ampoule to or near a target temperature.

21. A method according to claim 20, wherein:

said target temperature is approximately between 32 and 37 °C.

22. A method according to claim 20, wherein:

said first time is set when said ampoule is heated to or near said target temperature.

1 ABSTRACT OF THE DISCLOSURE
2

3 An analyzer apparatus includes a receptacle for an ampoule,
4 an analysis system, an incubator, and a master control. The
5 analysis system includes a light source and a photodetector
6 positioned such that the light from the light source passes
7 through the receptacle. The master control includes a display, a
8 timer, and a memory provided with a look-up table. During
9 operation, an ampoule containing a sample and an indicator which
10 changes color when a certain level of biological activity is
11 present in the sample is placed within the receptacles. The
12 analysis system is operated to transmit light at the predetermined
13 wavelength through the ampoule to the detector, and a maximum
14 amount of light passing through the ampoule is logged. The
15 incubator is operated to heat the receptacle and the ampoule
16 therein to a desired test temperature and the timer is started.
17 The analysis system periodically transmits light through the
18 ampoule. Increased biological activity in the ampoule causes a
19 color change in the indicator which reduces light transmission
20 through the ampoule. When the light detected is reduced relative
21 to the light transmitted by a predetermined percentage of the
22 maximum amount of light, the master control signals that the test
23 is complete. Based on the amount of time required for this to
24 occur, the master control determines from the look-up table the
25 bacterial content in the sample at the start of the test.

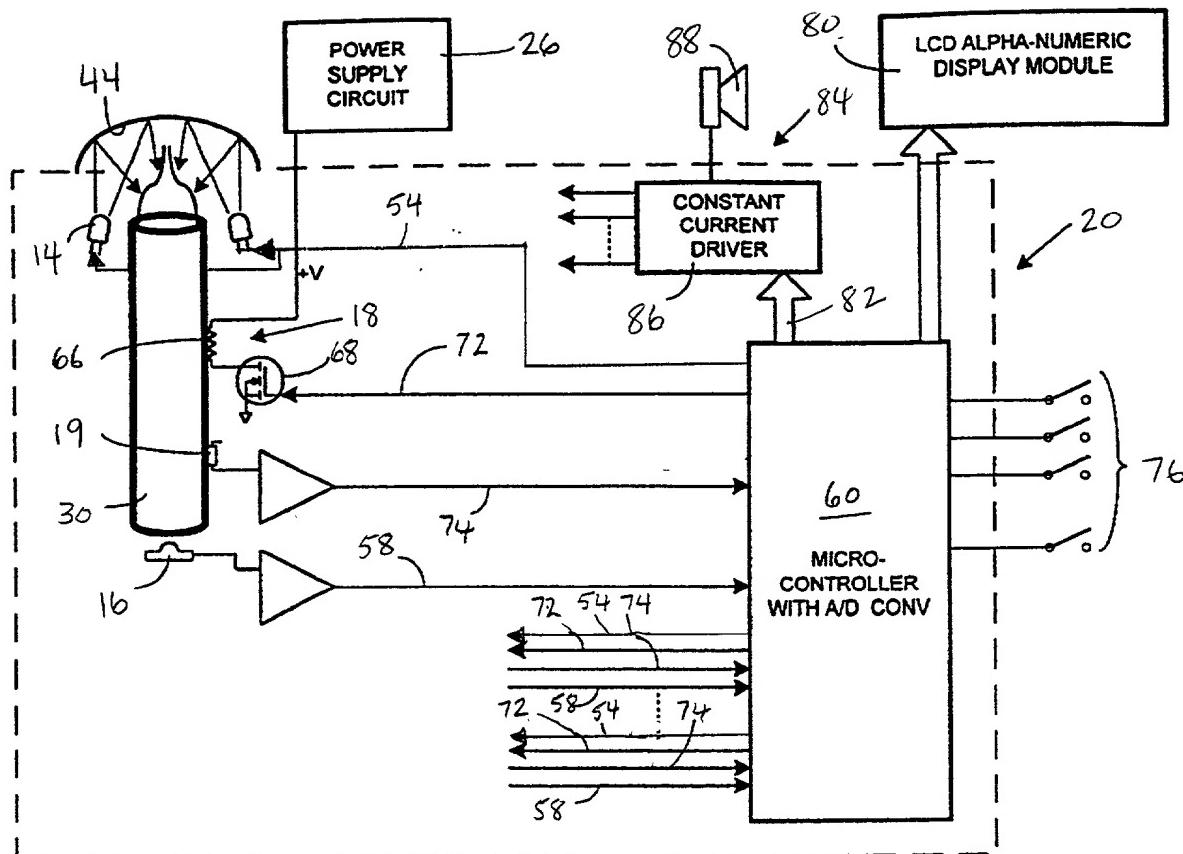


Fig 1

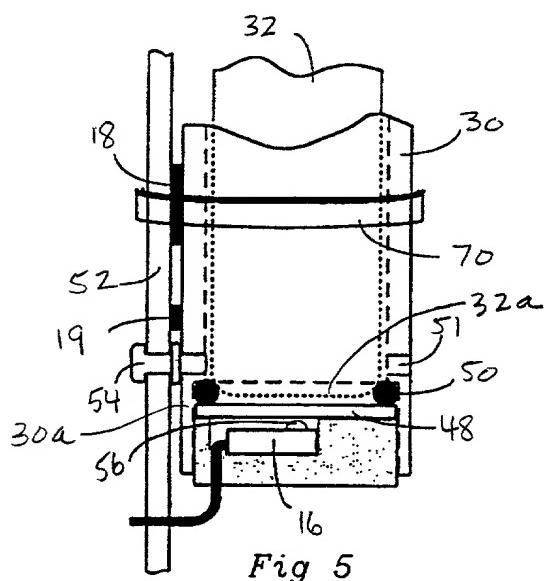


Fig 5

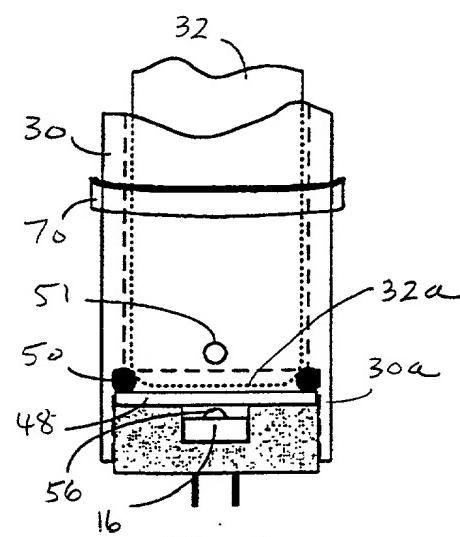
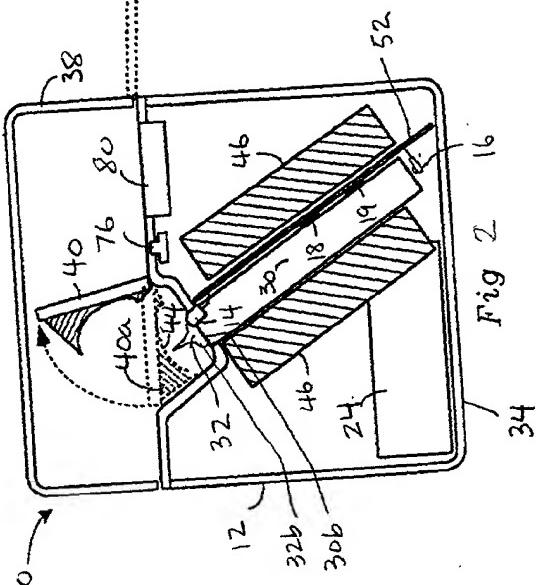
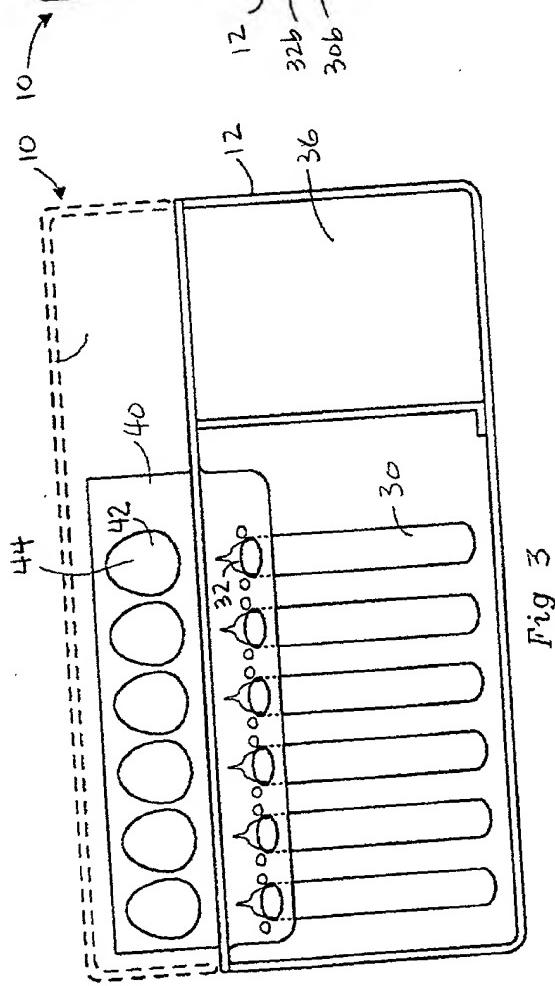
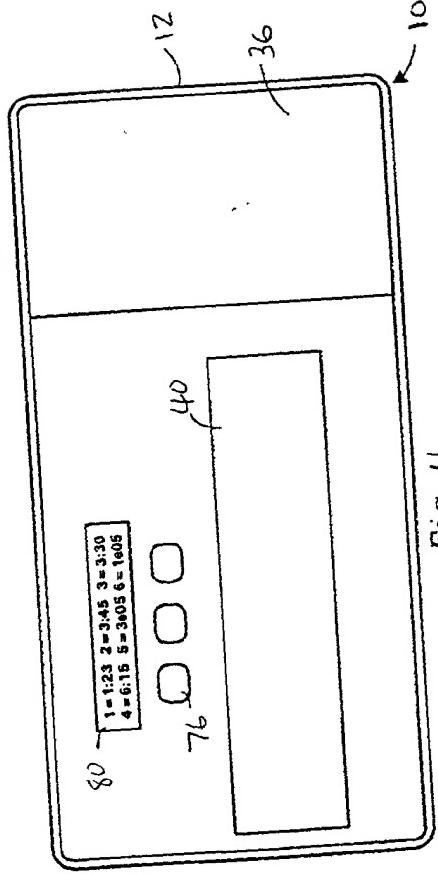
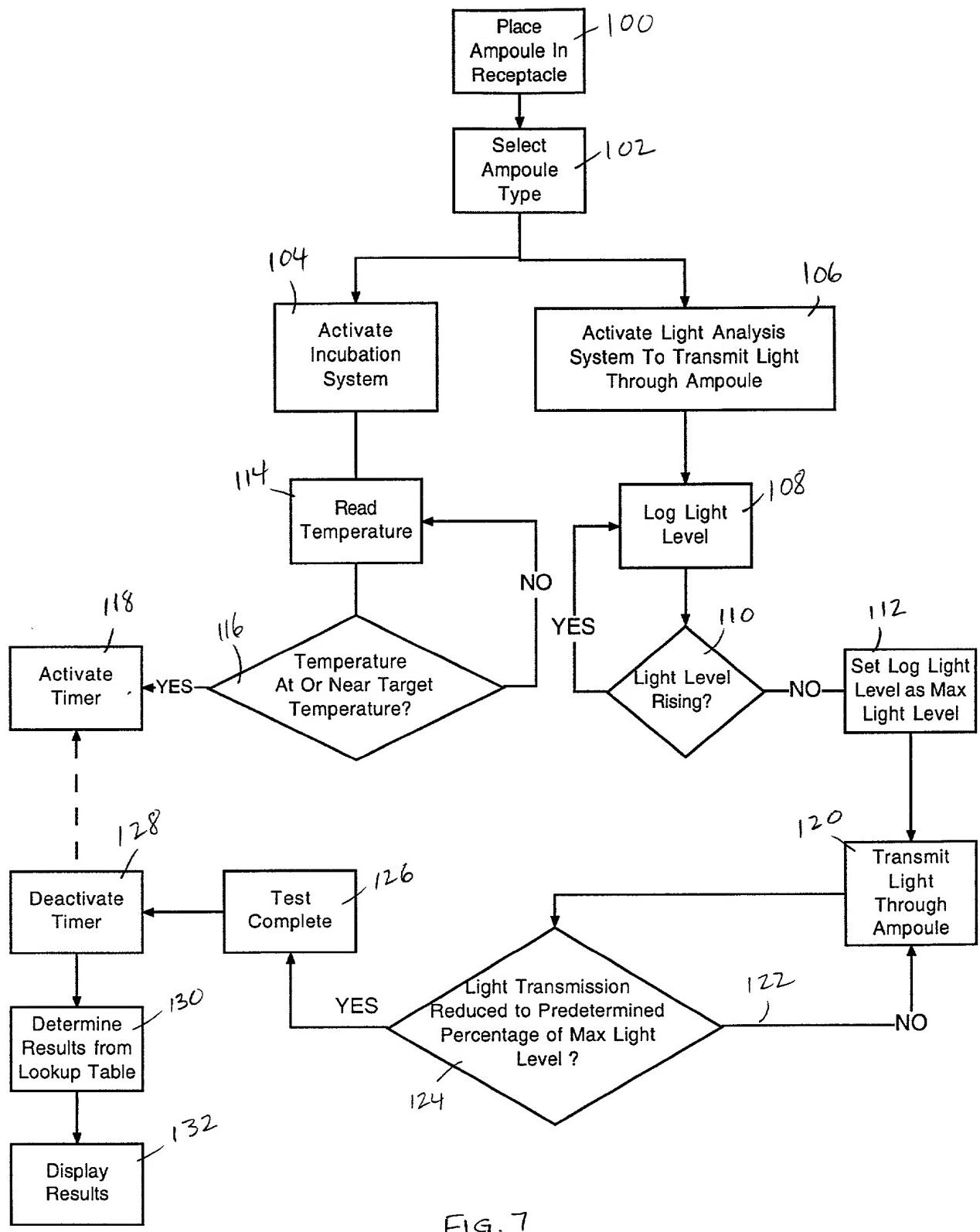


Fig 6

1 = 123 2 = 345 3 = 330
4 = 615 5 = 3605 6 = 1005





Docket No. PFE-002

DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

As below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name, and

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed for and for which a patent is sought on the invention entitled

AMPOULE ANALYZER APPARATUS,

the specification of which

[X] is attached hereto.

[] was filed on _____
as application Serial Number _____
and was amended on (if applicable) _____

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

I verify that I am qualified as an independent inventor under Title 37, Code of Federal Regulations, Section 1.9(c), and my obligation to assign rights to this invention, if any, is to a qualified small business concern under Title 37, Code of Federal Regulations, Section 1.9(d).

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

<u>Prior Foreign Application(s)</u>	<u>Priority Claimed</u>
_____ / _____ (Number) (Country)	_____ D/M/YR FILED [] YES [] NO
_____ / _____ (Number) (Country)	_____ D/M/YR FILED [] YES [] NO

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I

acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Ser. No) (Filing Date) (Status-Patented, pending, abandoned)

(Application Ser. No) (Filing Date) (Status-Patented, pending, abandoned)

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

David P. Gordon (29,996), David S. Jacobson (39,235), Thomas A. Gallagher (31,358)

Address all telephone calls to David P. Gordon at (203) 329-1160
Address all correspondence to David P. Gordon, Esq.

65 Woods End Road
Stamford, Connecticut 06905
U.S.A.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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DAVID P GORDON

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Docket No. PFE-002**DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY**

As below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name, and

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed for and for which a patent is sought on the invention entitled

AMPOULE ANALYZER APPARATUS,

the specification of which

[X] is attached hereto.

[] was filed on _____

as application Serial Number _____

and was amended on (if applicable) _____

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

I verify that I am qualified as an independent inventor under Title 37, Code of Federal Regulations, Section 1.9(c), and my obligation to assign rights to this invention, if any, is to a qualified small business concern under Title 37, Code of Federal Regulations, Section 1.9(d).

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Prior Foreign Application(s)Priority Claimed

(Number) _____
(Country) / / [] YES [] NO
 D/M/YR FILED

(Number) _____
(Country) / / [] YES [] NO
 D/M/YR FILED

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DAVID P GORDON

PAGE 03

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(Application Ser. No) (Filing Date) (Status-Patented, pending, abandoned)

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

FIRST INVENTOR

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SECOND INVENTOR

Signature Peter E. Rising Date 6/6/2000

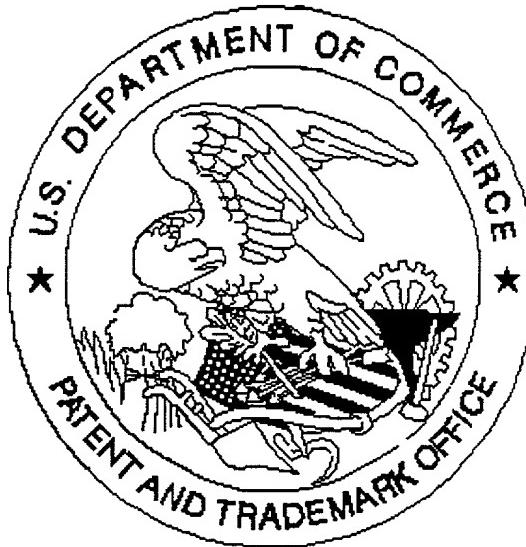
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Citizenship US

P.O. Address Same as address

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